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March 20, 2014

The Honorable Thomas P. Griesa
The Honorable Gabriel W. Gorenstein
United States District Court for the Southern
District of New York
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, NY 10007

VIA ECF

Re: Discovery dispute in Nos. 12-CV-8060, 12-CV-8115, 12-CV-8318,
12-CV-9261, and 12-CV-436

Dear Judge Griesa and Judge Gorenstein:

I write on behalf of Plaintiff Grünenthal in response to Defendants' letter to Judge Gorenstein pursuant to Local Rule 37.2 dated March 18, 2014. (Exh. 1). Despite Defendants' understanding that "discovery disputes in these cases are to be referred to Judge Gorenstein," Grünenthal addresses its response to both of Your Honors because the dispute alleged in Mr. Sabharwal's letter was already heard and resolved by Judge Griesa. As a result, Grünenthal believes that Defendants improperly seek to revive before Judge Gorenstein an already settled issue. Nonetheless, Grünenthal submits this letter according to Judge Gorenstein's individual practices should Your Honors disagree that the alleged discovery dispute has not been resolved.

Defendants' letter requests "a pre-motion discovery conference with this Court to address Plaintiff Grünenthal GmbH's refusal to produce any 30(b)(6) or 30(b)(1) testimony in this case." That request misstates the record. Grünenthal has not refused to produce *any* 30(b)(6) or 30(b)(1) testimony in this case. Instead, Grünenthal has already produced such deposition testimony taken from current and former employees on Grünenthal's tamper-resistant technology¹ in the prior Purdue litigations,² including all three inventors on the patents in suit

¹ The Grünenthal patents in suit include U.S. Patent Nos. 8,114,383; 8,309,060; and 8,192,722. As previously discussed before the Court, the prior Purdue litigations involved, *inter alia*, the '383 and '060 patents. See fn. 2. The '722 patent is a related family member with identical inventors. The '722 patent is owned by Grünenthal, but Plaintiff Endo the licensee of the '722 patent, not Plaintiff Grünenthal, asserts the '722 patent in these actions.

² The Purdue litigations were all before Judge Stein of this Court and include *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.* (12-cv-5083, 13-cv-4606), *Watson Laboratories, Inc. - Florida & Andrx Labs, LLC* (12-cv-3111, 13-cv-0762), *Par Pharmaceuticals* (continued...)

and one of the prosecuting attorneys.³ Each inventor was deposed at least twice in the Purdue litigations. (December 5, 2013, Hearing Tr. at 11:6-12; January 23, 2014, Hearing Tr. at 15:8-17). Grünenthal has agreed that those depositions can be used in these litigations as if they were taken here. (January 23, 2014, Hearing Tr. at 14:11-15:23; 19:22-20:21). In fact, each of the three inventors of the Grünenthal patents was deposed this year in the Purdue litigation with Teva Pharmaceuticals USA, Inc. (13-cv-4606), one of the Defendants in the litigations before Your Honors (12-cv-8060).

Thus, the alleged dispute boils down to whether Defendants are entitled to additional, duplicative depositions of Grünenthal in these litigations. Defendants have already broached that issue *twice* with Judge Griesa. The first time was at a hearing before Judge Griesa in December 2013. (December 5, 2013, Hearing Tr. at 10:2-19; 12:3-7). At that hearing, Grünenthal asserted that depositions of Grünenthal and its inventors in these cases is duplicative and undermines Judge Griesa's stated goal to simplify discovery. (*Id.* at 3:1-6; 11:6-12). In fact, Mr. Samay, counsel for Impax, apparently agreed and represented to Judge Griesa that no new deposition discovery of Grünenthal was necessary, stating that "[t]he focus of defendant's [*sic*] discovery is going to be on these new [Endo PK] patents, **not** the patents that were just mentioned by Grünenthal." (*Id.* at 12:9-24 (emphasis added)). In fact, Mr. Samay's clients, Impax Laboratories, Inc. and ThoRx Laboratories, Inc., have not joined Defendants' March 18th letter to the Court. After hearing both sides, Judge Griesa did not order Grünenthal to produce any witnesses, corporate or otherwise. (*See generally* December 5, 2013, Hearing Tr.) Indeed, based on Mr. Samay's representation, Judge Griesa ordered inventor depositions for only the Endo product impurities patent (the '482) and Endo PK patents (the '216 and '122 patents). (December 5, 2013, Hearing Tr. at 13:2-15:6).

Mr. Sabharwal renewed his request for additional discovery of Grünenthal at the next hearing before Judge Griesa. (January 23, 2014, Hearing Tr. at 11:18-13:5; 16:14-19:21; 20:22-21:23). Grünenthal reiterated that deposition discovery of it and its inventors is duplicative and unnecessary, especially since Grünenthal has already produced and will continue to produce deposition testimony specifically directed to the '383 and '060 patents from the Purdue cases. (*Id.* at 14:11-15:23; 19:22-20:21). Again, after hearing from both parties, Judge Griesa did not order any discovery of Grünenthal beyond the deposition transcripts Grünenthal had already

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Inc. (12-cv-5615, 13-cv-3374), *Impax Laboratories, Inc.* (13-cv-0763), and *Sandoz Inc.* (12-cv-5082, 12-cv-7582, 13-cv-7776).

³ Grünenthal will also produce the three remaining deposition transcripts from the three inventor depositions that occurred in January 2014. Grünenthal was waiting to produce them until the errata sheets were submitted, and those were only recently completed by the three witnesses and exchanged last Friday. Upon receipt of these transcripts, Defendants will have testimony from 9 witnesses, spanning 16 days.

agreed to produce. In fact, Judge Griesa interrupted Mr. Sabharwal's argument and ended the discussion about further depositions of Grünenthal. (*Id.* at 21:24-22:9). The transcripts of these hearings before Judge Griesa make clear that the issue of additional deposition discovery of Grünenthal has already been fully vetted twice before Judge Griesa and resolved. Consequently, Defendants' effort to attempt to resuscitate the issue before Judge Gorenstein is improper.

Defendants' actions outside the Court leading up to their March 18th letter further belie the propriety of their request for a pre-motion discovery conference before Judge Gorenstein. After the December 5th hearing on the issue, Defendants served on December 24th, a Rule 30(b)(6) Notice on Grünenthal. (Exh. 2, Notice of Deposition of Grünenthal GmbH Pursuant to Fed. R. Civ. P. 30(b)(6)). That Notice includes topics that, although phrased differently, are almost entirely duplicative of topics Purdue Defendants have already questioned Grünenthal about, despite Defendants' assertions to Judge Griesa that any additional discovery of Grünenthal would be non-duplicative. (Exhs. 3-5, First, Second, and Third 30(b)(6) Notices in Purdue; December 5, 2013, Hearing Tr. at 11:22-24, "and I think I speak for other defendants, that we are not going to endeavor to ask anything that is duplicative"; January 23, 2014, Hearing Tr. at 13:2-5, "then we are entitled to discovery on that, nonduplicative discovery"). Grünenthal has already produced 30(b)(6) deposition transcripts in these litigations and has agreed that Defendants may use them in these litigations as though they were taken here. (December 5, 2013, Hearing Tr. at 11:8-10; January 23, 2014, Hearing Tr. at 19:22-23). Thus, even after Judge Griesa's mandate to streamline and reduce discovery, and Grünenthal's production of deposition transcripts to do just that, Defendants served a duplicative 30(b)(6) Notice. Grünenthal responded to the Notice on January 2, 2014, refusing to produce a witness consistent with Judge Griesa's December 5th hearing. (Exh. 6, January 2, 2014, Letter to from J. Neth to U. Everett).

On January 10, 2014, the parties met and conferred regarding Ms. Neth's January 2nd letter about 30(b)(6) witnesses. Contrary to Defendants' assertion that "they would seek relief from the Court," following that call, Defendants did no such thing. Instead, a mere three days later, Defendants served a separate deposition notice on Grünenthal inventor Dr. Bartholomäus. (Exh. 7, Notice of Deposition dated January 13, 2013.) Thus, as of the January 10th meet and confer—the call that Defendants assert spurred the current pre-motion conference request—the issue of individual inventors' depositions was not even on the table.

Following that Notice, Grünenthal promptly responded and reiterated that no further depositions of Grünenthal witnesses under either F.R.C.P. 30(b)(6) or 30(b)(1) were warranted or ordered by the Judge. (Exh. 8, January 17, 2014, Letter from J. Neth to A. Lamut). Shortly thereafter, Mr. Sabharwal made his second plea to Judge Griesa for additional deposition discovery of Grünenthal (January 23, 2014, Hearing Tr. at 11:18-13:5; 17:4-12; 18:9-19:21; 20:22-21:23), and having already resolved the issue in December, the Court refused to grant the requested relief (*Id.* at 21:24-22:7).

A week later, Mr. Sabharwal tried again, demanding that Grünenthal, in view of Judge Stein's January 14th invalidity opinion concerning certain of the '383 patent claims, withdraw all of the asserted claims of the '383, '722, and '060 patents, or in the alternative "confirm that they will introduce no evidence or argument regarding the alleged differences, or provide discovery regarding those alleged differences." (Exh. 9, January 30, 2014, Letter from K. Sabharwal to B. Lewis). Grünenthal responded. (Exh. 10, February 5, 2014, Letter from J. Roscetti to K. Sabharwal). Less than a month later, the Court refused to entertain the very argument Mr. Sabharwal made in his January 30th letter. (February 20, 2014, Hearing Tr. at 43:22-25). Similarly, in a recent claim construction hearing before Judge Stein in the Purdue case, the Court refused to entertain a summary judgment motion to apply collateral estoppel to the '060 patent, preferring to try the case. (March 7, 2014 Claim Construction Hearing Tr. at 19-20, 41-42.)

Therefore, after three repeated and unsuccessful attempts to get what they want in hearings before Judge Griesa, Defendants now try to sidestep the record before Judge Griesa, posturing their present request to Judge Gorenstein as an open discovery dispute. Defendants say they want "either deposition discovery from Grünenthal on its patents and the Opana ER product, or an order that precludes Grünenthal from introducing new evidence regarding its patents." (Exh. 1, March 18, 2014, Letter from K. Sabharwal to J. Gorenstein at 2-3). But Defendants have numerous deposition transcripts of the inventors regarding the facts concerning the inventions and development that led to the Grünenthal patents. Grünenthal has indicated its intent to bring inventor Dr. Bartholomäus to trial to testify before Judge Griesa on the Grünenthal inventions, but "[a]s to the facts [Grünenthal wants] to introduce in this case, we are going to be introducing many of the facts that we introduced in the other [Purdue] case." (January 23, 2014, Hearing Tr. at 20:15-17.) Grünenthal should likewise not be precluded from introducing expert testimony, including testimony regarding the differences among the patent claims at issue. Plaintiffs' counsel have repeatedly asserted that such differences are matters for experts, and not fact witnesses. (January 23, 2014, Hearing Tr. at 20:9-14; 27:17-20). Expert discovery has not started in these litigations, so any attempt to preclude Grünenthal from introducing such expert testimony is premature.

Defendants' request for a pre-motion conference is but only one example of Defendants' refusal to streamline discovery and the issues for trial as repeatedly requested by Judge Griesa. Notably, at the end of the February 20th hearing, Judge Griesa scheduled a subsequent pretrial hearing on validity issues. (February 20, 2014, Hearing Tr. at 97:22-99:24). Mr. Black, counsel for Plaintiff Endo, requested that Defendants limit their invalidity contentions running in excess of 1500 pages, so that Plaintiffs could meaningfully respond in preparation for that next hearing. Instead, two weeks later two defendants supplemented their invalidity contentions by adding defenses and not removing any of the hundreds of allegedly prior art references. On the same day, Defendants sent a letter to Plaintiffs with "example" invalidity claim charts for only two of the patents in suit and requested that Plaintiffs provide reasons why they dispute Defendants' invalidity contentions. (Exh. 11, March 7, 2014, Letter from K. Warner to J. Loeb). Proving invalidity by clear and convincing evidence is Defendants' burden. It is not Plaintiffs' burden to

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prove validity. Patents are presumed to be valid. As the contentions now stand (hundreds of references and upwards of 1500 pages), it would be unduly burdensome for Plaintiffs to meaningfully respond before the scheduled April 2, 2014, hearing. (Exh. 12, March 13, 2014, Letter from J. Roscetti to K. Warner). Plaintiffs requested that Defendants provide a narrowed set of invalidity contentions, so that Plaintiffs could provide a response. (*Id.*) Rather than responding to this request to narrow the issues, Defendants instead seek yet again to obtain additional discovery that the Court previously denied.

As shown above, Defendants fail to articulate an actual, ripe discovery dispute. There is none. And as a result, Grünenthal believes that a pre-motion conference before Judge Gorenstein is unjustified. If Your Honors disagree, however, Grünenthal respectfully requests that it be given the opportunity to further clarify its positions at a pre-motion conference.

Respectfully submitted,



Basil J. Lewis

Enclosures

cc: Counsel of record